

## Notice of Allowability

Application No.

09/638,267

Applicant(s)

Stanton

Examiner

Arun Chakrabarti

Art Unit

1634



--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course.

**THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/8/03.
2. ☒ The allowed claim(s) is/are 122 and 123.
3. ☒ The drawings filed on Aug 14, 2000 are accepted by the Examiner.
4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0503</u> |
| 5 <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449), Paper No(s). _____          | 6 <input type="checkbox"/> Examiner's Amendment/Comment                                  |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance      |
| 9 <input type="checkbox"/> Other   |  |

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*Reasons for Allowance*

1. The following is an examiner's statement of reasons for allowance: In view of the amendment, the present invention is directed to a method for selecting a treatment for a patient suffering from a condition or disease, comprising:

determining whether cells of the patient contain at least two variances in the methylenetetrahydrofolate reductase gene, wherein the presence or absence of the variance in the gene is indicative of the effectiveness of the treatment for the condition or disease,

wherein the variance is selected from the group consisting of:

a) a variance that causes a G to be present at nucleotide 464 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

b) a variance that causes a U to be present at nucleotide 519 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

c) a variance that causes a C to be present at nucleotide 1059 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

d) a variance that causes an A to be present at nucleotide 1784 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

e) a variance that causes a C to be present at nucleotide 120 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

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Although Goyette et al. (Nature Genetics, (1994), Vol. 7, pages 195-200) teaches a method for selecting a treatment for a patient suffering from a condition or disease, comprising:

determining whether cells of the patient contain at least one variance in the methylenetetrahydrofolate reductase gene, wherein the presence or absence of the variance in the gene is indicative of the effectiveness of the treatment for the condition or disease,

wherein the variance is selected from a variance that causes a C to be present at nucleotide 120 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

Goyette et al. does not teach a) a variance that causes a G to be present at nucleotide 464 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

b) a variance that causes a U to be present at nucleotide 519 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

c) a variance that causes a C to be present at nucleotide 1059 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

d) a variance that causes an A to be present at nucleotide 1784 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene, as claimed in claims 122 and 123.

In view of the absence of either teaching or suggestion of such a) a variance that causes a G to be present at nucleotide 464 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

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b) a variance that causes a U to be present at nucleotide 519 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

c) a variance that causes a C to be present at nucleotide 1059 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene;

d) a variance that causes an A to be present at nucleotide 1784 of the mRNA (SEQ ID NO:1) encoded by the methylenetetrahydrofolate reductase gene, the present invention is novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose

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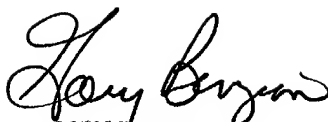
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telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

May 7, 2003

  
GARY BENZION, PH.D  
SUPERVISORY PATENT EXAMINER  
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